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**Lap-Band maker targets teenagers; Allergan asks the FDA to allow weight-loss surgery for people as young as 14. But that worries some experts.**

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For The Record; Los Angeles Times Thursday, May 26, 2011 Home Edition Main News Part A Page 4 News Desk 2 inches; 92 words Type of Material: Correction; **Lap-Band** device: An article in the May 24 Section A about efforts by Allergan Inc. to win approval for use of its **Lap-Band** weight-loss device in adolescents as young as 14 erred in describing the device. It is a silicone ring fitted around the stomach to reduce food intake, not a silicon ring. A brief news article in the May 16 Health section about a study of patients who received gastric bypass surgery for weight loss and those who received **Lap-Band** surgery, comparing their risks of developing alcoholism, made the same error.

With sales of its **Lap-Band** weight-loss device declining, Allergan Inc. has its eyes on a new set of potential customers -- overweight teenagers.

The Irvine company has asked the Food and Drug Administration to approve **Lap-Band** surgeries for adolescents as young as 14, and is conducting clinical trials on teenage patients, said Cathy Taylor, a company spokeswoman.

Allergan says the device -- a silicon ring fitted around the stomach to reduce food intake -- has proved a safe and effective way for obese adults to shed pounds. With an estimated one-third of U.S. children now overweight, the benefits should be extended to teenagers, Taylor said.

"We identified a significant need with this patient population in terms of the increasing rate of obesity in younger populations," Taylor said. "Obesity, if left untreated, correlates to life-threatening diseases."

But many doctors and health experts are concerned that there are not enough data about the **Lap-Band**'s long-term safety and effectiveness, something that would be particularly relevant when considering the device for children.

"It's hard to imagine taking a device ... and putting it around the stomach and giving it a warranty for 50 or 60 years," said Mary Brandt, head of adolescent bariatric surgery at Texas Children's Hospital in Houston.

Brandt said she believes that gastric bypass, surgically shrinking the stomach, is a better option because it does not require installing a foreign object in the body.

A recent European study found that many adult **Lap-Band** patients had "relatively poor long-term outcomes" and required additional surgeries to have the devices removed or replaced. Allergan took issue with that study, saying that it was based on too small a pool of patients and that the device has been improved in recent years.

The procedure is performed under general anesthesia, and complications can occur. In the last two years, four Southern California adults have died within days of undergoing **Lap-Band** surgery.

Health experts said **Lap-Band** surgery should be a last resort for the morbidly obese, only after less radical methods, such as diet and exercise, have been exhausted.

"I'm concerned that FDA approval would send the wrong message, that this is a safe way to lose weight," said Diana Zuckerman, president of the National Research Center for Women and Families. "There are risks

to this."

Doctors can already perform **Lap-Band** surgery on minors whose parents give their consent. FDA approval would allow Allergan for the first time to market the product for use on adolescents, said Jeffrey Gibbs, a former FDA attorney now in private practice in Washington specializing in medical device law. And it could make it more likely that insurers would pay for it, Gibbs said.

Taylor Blackburn of Palmdale had the **Lap-Band** installed in 2008, at age 14. Two years later, the Palmdale teenager had it removed after she experienced stabbing abdominal pains and diarrhea, her mother, Susan Blackburn, said.

"She got zero results. She was gaining weight," Blackburn said. "It was very discouraging for her."

Taylor Blackburn underwent gastric bypass surgery last year. She has lost 70 pounds, her mother said.

Allergan spokeswoman Cathy Taylor declined to comment, saying it "wouldn't be appropriate for us to comment on a patient when we are not privy to all the details."

More generally, Allergan executives have said the **Lap-Band** has proved effective at helping patients lose weight safely and has advantages over some other bariatric surgeries. Unlike bypass surgery, **Lap-Band** surgery is relatively easy to reverse and has a lower mortality rate, said Allergan Chief Executive David E.I. Pyott.

Jacy Johns, a Jacksonville, Fla., student, got the **Lap-Band** at her mother's urging when she was 15. She said it has transformed her life for the better.

Johns had tried Slim-Fast and Atkins diets without success. Before her June 2008 surgery, she weighed 225 pounds at 5 feet, 5 inches and looked to be developing diabetes. Afterward, she lost 95 pounds and joined her high school cross-country team. She recently attended prom.

"When I came back to school, everyone was blown away. Everyone was shocked," said Johns, now 18. "They told me I looked great. They wanted to know what I was doing."

Allergan has become a darling of Wall Street by catering to Americans' vanity with products including wrinkle-erasing Botox, Natrelle breast implants and Latisse eyelash lengthener. **Lap-Band** accounted for less than 5% of the company's \$4.9 billion in revenue last year. But the company is moving aggressively to expand that business.

Allergan's focus on teens marks its latest effort to expand the customer base for the weight-loss device. In February, the FDA approved the company's request to reduce the weight requirements for adults to be eligible for the **Lap-Band**, adding millions of Americans to its approved pool of potential customers.

The change meant that a 5-foot-10-inch man with one obesity-related illness now needs to weigh at least 209 pounds to qualify for the surgery, down from 243 pounds, according to a body mass index table available on the U.S. Department of Health and Human Services website.

More than 600,000 people worldwide have had **Lap-Band** surgeries since 1993. It was approved for use in the U.S. in 2001. But U.S. sales have slumped during the economic downturn. The procedure can cost as much as \$20,000, and some insurers won't cover it or require expensive co-payments. First-quarter sales of Allergan's obesity intervention products, primarily **Lap-Band**, were down 15% from a year earlier.

Allergan's Taylor declined to say how many U.S. children would be eligible for the surgery if the FDA lowers the age limit. About 12% of U.S. high school students are obese, according to a 2009 federal survey. Census data put the number of U.S. residents ages 14 to 17 at more than 16 million.

Teenagers would qualify only if they met specific weight requirements and had at least one obesity-related health condition such as heart disease or diabetes, Taylor said. They would need to be heavier than adults of the same height.

A girl who was 5 feet 6 inches would need to weigh 216 pounds -- 30 pounds more than an adult of that height -- and have one of the health conditions to qualify, according to the body mass index table. And youngsters would have to prove they have tried other weight-loss methods, Allergan's Taylor said.

"We're not talking about someone who's 20 pounds overweight who's looking to fit in a prom dress," she said. "You're looking at an adolescent who's morbidly obese, 100 pounds or more overweight, who has significant health problems because of their obesity."

Neither the FDA nor Allergan executives would say when they expect a decision regarding approval of the **Lap-Band** for teens. The company submitted its FDA application nearly two years ago, but it does not expect to conclude clinical trials until 2013. The approval process can take years, so the length of the process "is not unusual at all," said Stephen D. Terman, a medical device attorney in Washington.

Robert Cywes of Jacksonville, Fla., is one of the surgeons participating in Allergan's clinical trial of young patients. He said he has performed more than 500 of the procedures on adolescents, including Johns. Cywes said many children can't lose weight and keep it off because they're addicted to high-carbohydrate foods.

"Our adolescents are getting fatter, and there's really not anything outside of surgery that is reducing that in a significant way," he said.

The trend is discouraging to Russell Pate, a professor of exercise science at the University of South Carolina. He said the nation should be pushing diet and physical activity instead of making it easier for children to get weight-loss surgery.

"What we're saying is it's perfectly fine for us to become overweight because we're just going to apply treatment whenever that happens, and everyone will be good to go," Pate said. Obesity is "a preventable problem, and we really ought to be working to prevent it."

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PHOTO: TRANSFORMED: Jacy Johns of Jacksonville, Fla., underwent **Lap-Band** surgery at her mother's urging when she was 15 and said it has made her life better.; PHOTOGRAPHER: Jon M. Fletcher; GRAPHIC: Slimmed down; CREDIT: Los Angeles Times

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